GREER, BURNS & CRAIN, LTD.
300 South Wacker Drive, Suite 2500
Chicago, IL 60606

PATENT APPLICATION
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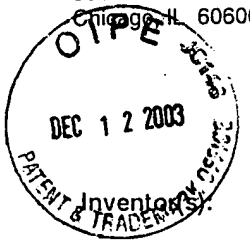

IN THE
UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Kircher et al.

Confirmation No.: 3314

Application No.: 09/729,498

Examiner: Gordon, Brian R

Filing Date: Dec. 4, 2000

Group Art Unit: 1743

Title: METHOD AND APPARATUS FOR CONTROLLING THE STRATEGY OF COMPOUNDING PHARMACEUTICAL ADMIXTURES

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TRANSMITTAL OF APPEAL BRIEF

Sir:

Transmitted herewith in **triplicate** is the Appeal Brief in this application with respect to the Notice of Appeal filed on Oct. 29, 2003.

The fee for filing this Appeal Brief is (37 CFR 1.17(c)) $330.00. A check in the amount of $330.00 is enclosed.

(complete (a) or (b) as applicable)

The proceedings herein are for a patent application and the provisions of 37 CFR 1.136(a) apply.

( ) (a) Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)-(d) for the total number of months checked below:

- ( ) one month
- ( ) two months
- ( ) three months
- ( ) four months

( ) The extension fee has already been filled in this application.

(X) (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

Please charge to Deposit Account 07-2069 the sum of _____. At any time during the pendency of this application, please charge any fees required or credit any over payment to Deposit Account 07-2069 pursuant to 37 CFR 1.25. Additionally please charge any fees to Deposit Account 07-2069 under 37 CFR 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees. A duplicate copy of this sheet is enclosed.

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Respectfully submitted,

By _____
Roger D. Greer

Attorney/Agent for Applicant(s)
Reg. No. 26,174

Date: December 10, 2003

Telephone No.: (312) 360-0080

NU-5532 PATENT

IN THE UNITED STATES PATENT AND TRADMARK OFFICE

Applicant:	Kircher et al.	)
Serial No.:	09/729,498	)
Filed:	December 4, 2000	)
For:	METHOD AND APPARATUS FOR CONTROLLING THE STRATEGY OF COMPOUNDING PHARMA-CEUTICAL ADMIXTURES	)
Group Art Unit:	1743	)
Examiner:	Gordon, Brian R.	)

I hereby certify that this paper is being deposited with the United States Postal Services as FIRST-CLASS mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date.

12/9/03 Date

Registration No. 28174

APPELLANT'S BRIEF ON APPEAL UNDER 37 C.F.R. §1.192

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Appeal Brief is in support of Applicant's Notice of Appeal dated October 29, 2003 from the final rejection dated October 6, 2003.

12/16/2003 MDAMTE1 00000058 09729498
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APPEAL BRIEF

REAL PARTY IN INTEREST

The real party in interest in this application is Baxter International Inc., One Baxter Parkway, Chicago, IL 60015.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences which will directly affect, be directly affected by, or have any bearing on the Board's decision in this pending appeal.

STATUS OF CLAIMS

This application was originally filed with 31 claims, only one of which has been amended, namely, claim 11 to correct a grammatical error. The rejections of all claims 1-31, inclusive, are appealed.

SUMMARY OF THE INVENTION

The present invention is an improved method and apparatus for preparing and accounting for parenteral nutritional solutions and for reducing instances of incompatibility, which preferably includes a software implementation of the method that will accommodate

many known active ingredients and other components that are set forth in various prescription admixtures. The apparatus and method implement strategies for preparing prescriptions for parenteral admixtures, for controlling the compounding apparatus, and for properly accounting for the prescribed admixture, with the strategies being implemented in computer software.

More particularly, the invention involves an apparatus (or method) for controlling pharmaceutical compounders that transfer prescribed amounts of pharmaceutical components from individual source containers to a final container to prepare a prescription admixture, that comprises computing means having a memory for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, with the memory includes data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, as well as data concerning the operating characteristics of the compounders. The computing means receives a prescription admixture, identifies the pharmaceutical components of it, determines the compatibility of the pharmaceutical components relative to one another, determines the order in which the components are transferred in preparing the prescription admixture, and communicates the instructions for preparing the prescription admixture to the compounders that are to be used in preparing the prescription admixture.

With regard to reading the claim elements on the specification, the following claim charts for claims 1 and 24 is believed to be instructive:

Claim	Specification
1. Apparatus (Fig. 1, ref 10) for use in controlling the operation of at least one pharmaceutical compounder (Fig. 1, ref 10) adapted to selectively transfer prescribed amounts of pharmaceutical components from individual source containers (Fig. 2, ref 30; Fig. 3, ref 56) through elongated hollow transfer means (Fig. 2, ref 32; Fig. 3, ref 54) to a final container Fig. 2, ref 46; Fig. 3, ref 58) in order to prepare a prescription admixture, said apparatus comprising:	Pg 10, ln 25 to pg 11, ln 14
computing means having memory means for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, said memory means including data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, and data concerning the operating characteristics of at least one of the compounders that the apparatus is adapted to control;	pg 11, ln 3-14. Generally: pg 15, ln 12 to pg 18, ln 5. Compatability of final prescription: pg 18, ln 13 to pg 19, ln 7. Calcium phosphate: pg 19, ln 7 to pg 21, ln 4. Compatability during compounding: pg 21, ln 5 to pg 22, ln 3. "Data relating..": pg 22, ln 4 to pg 23, ln 15. "operating characteristics...": pg 25, ln 13 to pg 26, ln 18.

said computing means including at least one communication port for establishing a communication link with each compounder that is to be controlled;	pg 11, ln 7-12. Fig. 1, ref 22.
said computing means being adapted to receive a prescription admixture, identify the pharmaceutical components thereof, determine the compatibility of the pharmaceutical components relative to one another, determine the order in which the components are transferred in preparing the prescription admixture, and communicate the instructions for preparing the prescription admixture to the compounders that are to be used in preparing the prescription admixture.	"receive and identify": pg 16, ln 1 to pg 17, ln 13. "determine compatibility": pg 18, ln 13 to pg 19, ln 7 and pg 21, ln 5 to pg 22, ln 3. "determine order": pg 23, ln 11 to pg 24, ln 25. "communicate instructions": pg 28, ln 2-7; pg 27, ln 6-8; pg 35, ln 11-19.

24. A method of controlling the operation of at least one pharmaceutical compounder (Fig. 1, ref 12, 14, 16) adapted to selectively transfer prescribed amounts of pharmaceutical components from individual source containers (Fig 2, ref 30, Fig 3, ref 56) through elongated hollow transfer means (Fig 2, ref 32, Fig 3, ref 54) to a final container (Fig 2, ref 46, Fig 3, ref 58) in order to prepare a prescription admixture, the method utilizing a computing means having memory means (Fig. 1, 10) for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, with the memory means including data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, and data concerning the operating characteristics of at least one of the compounders that the apparatus is adapted to control, the computing means including at least one communication port for establishing a communication link with each compounder that is to be controlled, the method comprising the steps of:

"selectively transfer": pg 16, ln 1 to pg 17, ln 13. "data relating..": pg 22, ln 4 to pg 23, ln 15. pg 11, ln 3-14. "operating characteristics...": pg 25, ln 13 to pg 26, ln 18. "communication port": pg 11, ln 7-12. Fig. 1, ref 22

receiving a prescription admixture in the computing means;	"receive and identify": pg 16, ln 1 to pg 17, ln 13.
identifying and determining the amounts of the pharmaceutical components of the prescription admixture;	"receive and identify": pg 16, ln 1 to pg 17, ln 13.
determining the compatibility of the pharmaceutical components relative to one another;	"determine compatibility": pg 18, ln 13 to pg 19, ln 7 and pg 21, ln 5 to pg 22, ln 3.
determining the order in which the components are transferred during the preparation of the prescription admixture; and,	"determine compatibility": pg 18, ln 13 to pg 19, ln 7 and pg 21, ln 5 to pg 22, ln 3.
communicating the instructions for preparing the prescription admixture to the at least one compounder that is to be used in preparing the prescription admixture.	"communicate instructions": pg 28, ln 2-7; pg 27, ln 6-8; pg 35, ln 11-19.

ISSUES PRESENTED

1. Whether claims 1-4, 10, 24-27 were properly rejected under 35 U.S.C. § 102(b) as being anticipated by Lewis et al. U.S. Patent No.5,228,485.

2. Whether claims 5-23 and 28, 30-31 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Lewis et al. as applied to claims 1-4, 10, 24-27

and 29 above and further in view of *Multitask Operating System for Automix® Compounders Version 2.30*, Baxter, May 1999.

GROUPING OF CLAIMS

Applicants contend that claims 1-5, 10-12 and 24-27 stand or fall together. Applicants also contend that claims 6-9 and 28 stand or fall together; claims 9, 13, 30 and 31 stand or fall together; claim 14 alone stands or falls; claims 15-18 stand or fall together; claims 19-21 stand or fall together; claim 22 alone stands or falls; claim 23 alone stands or falls; and claim 29 alone stands or falls.

ARGUMENT

I. The rejection of claims 1-4, 10, 24-27 under 35 U.S.C. § 102(b) as being anticipated by Lewis et al. U.S. Patent No.5,228,485. was improper.

The examiner's rejection of claim 1 on the basis of the Lewis et al. U.S. Patent No.5,228,485 (hereinafter "Lewis") is improper because it grossly exaggerates the Lewis reference far beyond what is justified. While the examiner has provided extensive comments concerning Lewis, it is clear that neither Lewis nor the Baxter reference used in the § 103 rejections of other claims, anticipate, teach or suggest several features of the claims, including the two independent claims 1 and 24.

The examiner's characterization of the Lewis reference misrepresents and distorts the functionality and capabilities of the prior art that is relied upon. Applicants are well aware of the content of this prior art because the Lewis patent is assigned to Clintec Nutrition Co., which is related to the assignee of the present invention and the Baxter reference is an operating manual of one of the assignee's own products that is also referred to in the present application.

The present invention significantly advances the state of the art and includes features and functionality that are totally missing in Lewis and Baxter. During the prosecution of this application the examiner had underlined the word "incompatible" several times during the characterization of the Lewis reference as if the knowledge that some drugs are not compatible with one another, in and of itself, is significant to the present invention. It simply is not.

Claim 1 claims an apparatus for use in controlling the operation of at least one pharmaceutical compounder which comprises, *inter alia*, "computing means including memory means for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, said memory means including data relating to a plurality of pharmaceutical components" and wherein "said computing means being adapted to receive a prescription admixture, identify the pharmaceutical components thereof, determine the compatibility of pharmaceutical components relative to one another, determine the order in which the components are transferred in preparing the prescribed admixture".

As is clearly set forth in the claim, it is the *computing means* that performs these functions, not a technician or operator. As is set forth in the specification, data relating to the pharmaceutical components is stored in the memory means and when a prescription is input into the apparatus, the computing means identifies the pharmaceutical components, determines their compatibility relative to one another and determines the order in which the components are transferred in preparing the prescription admixture. This is done in the course of its operation.

Lewis simply does none of this. The Lewis apparatus must be programmed by an operator using a keyboard and possibly another computer, but neither the master microprocessor nor the pumping microprocessor has the capability to identify the specific pharmaceutical components, determine their compatibility and determine the order in which the components are transferred to the final bag during compounding. To the extent that incompatibility of components is an issue, it must be determined to be so by the operation during the input process. The processing means of either of the Lewis or Baxter references cannot determine incompatibility. There is no discussion whatsoever in either reference about a processing means determining compatibility or determining the order of transfer of components because neither of them has this functionality. Lewis alludes to the compatibility issue at column 31, lines 7-10 where it states "normally, a rinse will not be conducted unless the next fluid to be pumped is incompatible with the previous fluid, or if the previous fluid pumped was the last fluid to be pumped." In the rinse operation discussion

at column 31, lines 58-64, it is clear that rinsing is operator defined: "As can be seen in Fig. 37, the first function performed during the rinsing operation is to perform a check to determine if the chamber needs to be rinsed after fluid has been transmitting from a particular source container. *An operator of the device may indicate that a rinse is required when information is being entered into the device*".

There is also little discussion as to the order in which components are transferred. Presumably, the order can be controlled, but it is done *by an operator* during setup. At column 20, lines 7-10 of Lewis, it states "the keyboard programming mode is the mode in which *an operator can input information* into the device to cause the device to transfer specific amounts of fluid from specific individual source containers in the receiving container." Also, at column 21, lines 13-20, the operation is described: "the *programmer may then use the keyboard illustrated in Fig. 22 to program* the amount of fluid to be transferred from that particular source container to the receiving container. The programmer may either enter the volume or the specific gravity of the fluid to be transferred. Typically, *during initial setup of the device, the specific gravity for each source container will be initially programmed by the operator.*" And finally, at column 21, lines 45-47, "*after the operator has completed entering information* into the device for all the source containers, the operator may then press the start key 284."

It is clear that the Lewis apparatus only operates in a particular manner that is established by the operator programming its operation. The operator keys in components and

presumably their order as a result of operator knowledge of compatibility or incompatibility of components relative to one another determines the order in which they are transferred and if the operator believes that a rinse should be done, programs that as well. The Baxter reference does not supply any of the deficiencies of Lewis. For the above reasons, claim 1 is neither anticipated, taught nor suggested by Lewis, Baxter, applied singularly or in combination with any of the other references of record.

Independent claim 24 is directed to a method for controlling the operation of at least one pharmaceutical compounder wherein the method utilizes a computing means having memory means for storing, *inter alia*, data relating to a plurality of pharmaceutical components that may be transferred to prepare the prescription admixture and which comprises the steps of identifying and determining the amounts of the pharmaceutical components of the prescription admixture, determining the compatibility of the pharmaceutical components relative to one another as well as the step of determining the order in which the components are transferred during the preparation of the prescription admixture. The computing means performs these identifying and determining steps. Lewis simply does not perform these steps. To the extent that they are carried out at all, they are carried out by an operator and certainly not by the microprocessors in the Lewis system. For these reasons as well as the reasons more fully described with regard to claim 1, it is believed that claim 24 is neither anticipated, taught nor suggested by Lewis or Baxter, applied singularly or in combination with one another or with the other references of record.

Claim 2 recites the functionality that the computing means is adapted to convert the amount of each component to a measure in which the compounder that is to prepare the prescription and mixture is able to transfer. This is simply not taught or suggested by Lewis. Lewis is a self-contained system which requires inputting that is done by a keyboard entry device. The only reference to another source is that "another method of entering the information into the device is through a computer terminal . . .", column 19, lines 14-21. The functionality of claim 2 is not addressed and therefore cannot be taught or suggested by Lewis, Baxter or any of the other references of record.

Claim 3 recites that the computing means is adapted to convert amounts of component volume set forth in the prescription admixture to a weight measure by multiplying the specific gravity of the component by the volume set forth in the prescription admixture. Lewis is not believed to teach or suggest this feature for the reason that an operator either inputs volume or specific gravity information into the apparatus during initial setup of the apparatus (column 21, lines 15-18).

Claim 4 is also not taught or suggested by any of the references of record. Neither Lewis nor Baxter have data relating to a plurality of pharmaceutical components that comprise a database having a plurality of compatibility groups as well as data specifying the compatibility and/or incompatibility of each group with respect to the other groups. It is simply not present or suggested by either reference.

Claim 5 further recites that at least the first one of the compatibility groups comprises components which include lipids and the second one of said compatibility groups comprises a component that is sterile water. Again neither Lewis nor Baxter have a database, much less a database that suggests these characteristics.

The Group consisting of Claims 9, 13, 30 and 31

Claim 9 specifies further functionality relating to the order of transfer that can vary depending upon whether a component that contains lipids is present in the prescription. The microprocessors of the Lewis or Baxter systems simply are not programmed to perform this functionality, and simply do not even remotely suggest this capability.

Claim 13 cites additional functionality wherein the computing means is adapted to examine the prescription admixture and determine whether lipid components are a part of it as well as making other determinations as recited. Neither Lewis, Baxter nor any of the other references even remotely teach or suggest this functionality.

With regard to claims 30 and 31, these claims were rejected under 35 U.S.C § 103 as being obvious over Lewis and Baxter. Nontheless, the functionality set forth in these claims is similar to that set forth in claims 9 and 13, and for the same reasons it is believed that these claims are not remotely taught or suggested by any of these references of record.

II. The rejection of claims 5-23 and 28, 30-31 under 35 U.S.C. § 103(a) as being unpatentable over Lewis et al. as applied to claims 1-4, 10, 24-27 and 29 above and further in view of *Multitask Operating System for Automix® Compounders Version 2.30*, Baxter, May 1999 was improper.

The Group consisting of claims 6-8 and 28.

With regard to claim 6, neither Lewis nor Baxter even remotely teach or suggest the computing means determining the order in which components are transferred so that the order is in accordance with a set of general rules of order of admixing as specified in this claim. These references do not have computing means that determine the order of transfer as set forth above, and also certainly do not determine the order such that it is in accordance with a set of general rules of order of admixing.

Claim 7 further specifies the features and functionality of the computing means determining the number and location of rinses that are to be made during the order of transfer of components. It simply is not taught or suggested by Lewis or Baxter or any of the other references of record. The number and location of rinses is decided by and is manually entered by an operator for every prescription.

Claim 28 is similar to claim 6 and should be allowable for the same reasons.

Claim 14

Claim 14 describes the functionality of the computing means being adapted to receive a plurality of prescription admixtures and to order them into a queue for preparation

and to reorder them based upon commonality of predetermined components as recited in the claim. Neither Lewis, Baxter nor any of the other references of record even remotely teach or suggest this functionality.

The Group consisting of claim 15-18

Claim 15 recites that the computing means is adapted to retrieve data relating to a patient profile as well as data relating to a plurality of categories of patients and make comparisons as recited in the claims. Lewis and Baxter simply do not have this capability and therefore cannot teach or suggest this claim.

With regard to claim 18, it is believed that Lewis and Baxter do not teach or suggest preparing a report containing the information as set forth in this claim.

The Group consisting of claims 19-21

Claim 19 defines added functionality that is performed by the computing means wherein it is adapted to retrieve data relating to a patient profile for which a prescription admixture is to be prepared, wherein the patient profile data includes at least the patient's name, age and weight, said computing means being adapted to retrieve data relating to limits of amounts of admixture components that can be added to a particular patient's prescription admixture, said computing means being adapted to compare the amounts of components in a prescription admixture for a patient and require an authorized entry of data explaining the

rationale of exceeding one or more of such limits. Neither Lewis or Baxter have anything close to this functionality, particularly with regard to requiring an authorized entry of data explaining the rationale of exceeding one or more of such limits and therefore fail to teach or suggest this claim.

Claim 22

Claim 22 further specifies that said memory means includes data relating to the amount of fluid that is required to prime the compounder from a source container through the elongated hollow transfer means to the final container, said processing means being adapted to increase the amount of a component by the amount that is required to prime the compounder. There is nothing in Lewis or Baxter that even remotely suggests increasing the amount of a component by the amount that is required to prime the compounder.

Claim 23

Claim 23 further specifies that the processing means is adapted to receive a switchable input relating to the preparation of an admixture prescription that calls for a first component in a predetermined amount, an amount of diluent for said first component and one or more additional components in relatively small amounts, wherein the total admixture prescription is to be a predetermined total amount, said computing means being adapted to use the volume of said one or more additional components in relatively small amounts as a

substitute for the same volume of diluent so that the predetermined total amount is not exceeded. This functionality of using the volume of said one or more additional components in relatively small amounts as a substitute for the same volume of diluent so that the predetermined total amount is not exceeded is not remotely suggested by Lewis or Baxter.

Claim 29

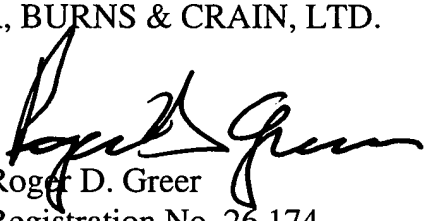
Claim 29 further defines the order determining step to comprise determining the order of admixing whereby components within groups that are compatible with one another are added sequentially to the final container, so that the number of rinses are minimized, the rinses being made to cleans the hollow transfer means near the final container due to incompatibility of a component of one group relative to a component in another group that is next in order to be transferred. While neither Lewis or Baxter have a computing means that determine the order of admixing as previously discussed, they certainly do not have the additional functionality of using sequentially adding compatible groups to minimize the number of rinses that are required. Neither Lewis nor Baxter remotely teach or suggest the functionality described in this claim.

CONCLUSION

For the above reasons, the Applicant respectfully requests that the Board reverse the Examiner's § 102 and 103 rejections of all pending claims 1-31

Respectfully submitted,

GREER, BURNS & CRAIN, LTD.

By 

Roger D. Greer
Registration No. 26,174

December 10, 2003

300 South Wacker Drive, 25th Floor
Chicago, Illinois 60606
(312) 360-0080
Facsimile: (312) 360-9315

APPENDIX

1. Apparatus for use in controlling the operation of at least one pharmaceutical compounder adapted to selectively transfer prescribed amounts of pharmaceutical components from individual source containers through elongated hollow transfer means to a final container in order to prepare a prescription admixture, said apparatus comprising:

computing means having memory means for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, said memory means including data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, and data concerning the operating characteristics of at least one of the compounders that the apparatus is adapted to control;

said computing means including at least one communication port for establishing a communication link with each compounder that is to be controlled;

said computing means being adapted to receive a prescription admixture, identify the pharmaceutical components thereof, determine the compatibility of the pharmaceutical components relative to one another, determine the order in which the components are transferred in preparing the prescription admixture, and communicate the instructions for preparing the prescription admixture to the compounders that are to be used in preparing the prescription admixture.

2. Apparatus as defined in claim 1 wherein said computing means is adapted to convert the amount of each component to a measure in which the compounder that is to prepare the prescription admixture is able to transfer.

3. Apparatus as defined in claim 2 wherein said computing means is adapted to convert amounts of component volume set forth in a prescription admixture to a weight measure by multiplying the specific gravity of the component by the volume set forth in the prescription admixture.

4. Apparatus as defined in claim 1 wherein said data relating to a plurality of pharmaceutical components comprises a database having a plurality of compatibility groups, with each group having at least one of said pharmaceutical components, said database also having data specifying the compatibility and/or incompatibility of each group with respect to other groups.

5. Apparatus as defined in claim 4 wherein at least a first one of said compatibility groups comprises components which include lipids, and a second one of said compatibility groups comprises a component that is sterile water.

6. Apparatus as defined in claim 4 wherein said computing means determines the order in which the components are transferred so that the order is in accordance with a set of general rules of order of admixing, which general rules comprise:

phosphate salts are added before calcium salts;

calcium phosphate solubility is made based upon the volume of solution in the prescription admixture at the time calcium is added; and,

calcium is the last additive to the prescription admixture.

7. Apparatus as defined in claim 6 wherein said computing means determines the number and location of rinses that are to be made during the order of transfer of components, with a rinse being a cleansing of at least a portion of the elongated hollow transfer means near the final container with a solution that is compatible with the next succeeding component that is to be transferred to the final container.

8. Apparatus as defined in claim 6 wherein said cleansing solution is taken from one of the individual source containers or the final container.

9. Apparatus as defined in claim 4 wherein said computing means includes at least one port for receiving input data for selecting whether a pharmaceutical component that includes lipids will determine the order of transfer such that the lipid containing component is transferred one of either first or last relative to all other pharmaceutical components.

10. Apparatus as defined in claim 1 wherein said communication link can be comprised of at least one of an internet connection, a local area network connection and a wireless connection.

11. Apparatus as defined in claim 1 wherein said apparatus is adapted to be used by users in at least two locations, wherein each location can have at least one compounder, and a printer for printing labels, a terminal with a display and entry device for inputting prescription admixtures and selectable settings relating to the operation of the apparatus and compounders.

12. Apparatus as defined in claim 11 wherein said computing means is adapted to control two compounders at each location, with one compounder being adapted to transfer components at a flow rate that is significantly higher than the other compounder.

13. Apparatus as defined in claim 9 wherein said computing means is adapted to examine the prescription admixture and determine whether lipid components are a part thereof, determine whether the user objects to the subsequent prescription admixture that will be prepared having a probable hazy appearance because of the presence of a lipid component in the prescription admixture presently being prepared, terminate the preparation of the prescription admixture in the event the user indicates an objection and issue a warning of such probable hazing in the event the user indicates no objection.

14. Apparatus as defined in claim 9 wherein said computing means is adapted to receive a plurality of prescription admixtures and order them into a queue for preparation, said computing means being adapted to examine each prescription admixture that is in the queue and determine the commonality of predetermined components therein, and to reorder the prescription admixtures in said queue to group together said prescription admixtures which have such commonality of predetermined components.

15. Apparatus as defined in claim 1 wherein said computing means is adapted to retrieve data relating to a patient profile for which a prescription admixture is to be prepared, wherein the patient profile data includes at least the patient's name, age and weight, said computing means being adapted to retrieve data relating to a plurality of categories of patients, with each category containing predetermined limits of admixture components that are specific to each category, said computing means being adapted to compare the amounts of components in a prescription admixture for a patient in one of said categories and provide a signal when a component is outside of the predetermined limits for said component in the prescription admixture.

16. Apparatus as defined in claim 15 wherein said categories of patients comprise adult, pediatric, neo-natal and premature patients.

17. Apparatus as defined in claim 15 wherein said signal is adapted to prevent the prescription admixture to be prepared.

18. Apparatus as defined in claim 15 wherein said patient's profile data further includes a history of the patient's weight and admixture prescriptions over a period of time, said processing means being adapted to prepare a report concerning the patient, including a projection of the patient's weight at some time in the future.

19. Apparatus as defined in claim 1 wherein said computing means is adapted to retrieve data relating to a patient profile for which a prescription admixture is to be prepared, wherein the patient profile data includes at least the patient's name, age and weight, said computing means being adapted to retrieve data relating to limits of amounts of admixture components that can be added to a particular patient's prescription admixture, said computing means being adapted to compare the amounts of components in a prescription admixture for a patient and require an authorized entry of data explaining the rationale of exceeding one or more of such limits.

20. Apparatus as defined in claim 19 wherein an authorized entry of data is entry of data by at least a physician or pharmacist.

21. Apparatus as defined in claim 19 wherein an absence of required data explaining the rationale of exceeding one or more of such limits results in said computing means terminating the preparation of said admixture prescription.

22 Apparatus as defined in claim 1 wherein said memory means includes data relating to the amount of fluid that is required to prime the compounder from a source container through the elongated hollow transfer means to the final container, said processing means being adapted to increase the amount of a component by the amount that is required to prime the compounder.

23. Apparatus as defined in claim 1 wherein said processing means is adapted to receive a switchable input relating to the preparation of an admixture prescription that calls for a first component in a predetermined amount, an amount of diluent for said first component and one or more additional components in relatively small amounts, wherein the total admixture prescription is to be a predetermined total amount, said computing means being adapted to use the volume of said one or more additional components in relatively small amounts as a substitute for the same volume of diluent so that the predetermined total amount is not exceeded.

24. A method of controlling the operation of at least one pharmaceutical compounder adapted to selectively transfer prescribed amounts of pharmaceutical components from individual source containers through elongated hollow transfer means to a final container in order to prepare a prescription admixture, the method utilizing a computing means having memory means for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, with the memory means including data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, and data concerning the operating

characteristics of at least one of the compounders that the apparatus is adapted to control, the computing means including at least one communication port for establishing a communication link with each compounder that is to be controlled, the method comprising the steps of:

receiving a prescription admixture in the computing means;

identifying and determining the amounts of the pharmaceutical components of the prescription admixture;

determining the compatibility of the pharmaceutical components relative to one another;

determining the order in which the components are transferred during the preparation of the prescription admixture; and,

communicating the instructions for preparing the prescription admixture to the at least one compounder that is to be used in preparing the prescription admixture.

25. A method as defined in claim 24 wherein the step of identifying and determining the amounts includes the step of converting the amount of each component to a measure in which the compounder that is to prepare the admixture prescription is able to transfer.

26. A method as defined in claim 24 wherein the data relating to a plurality of pharmaceutical components comprises a database of pharmaceutical components that are categorized into a plurality of groups, with the components of each group having common compatibility characteristics, said database having data specifying the compatibility and/or incompatibility of each group relative to other groups, said compatibility determining step further comprising:

examining the admixture prescription to identify the particular groups of components that are present therein, and the compatibility characteristics of each group relative to the other identified groups.

27. A method as defined in claim 26 wherein said order determining step further comprises: determining the order of admixing so that components within groups that are compatible with one another are added concurrently or sequentially to the final container consistent with known general rules of mixing.

28. A method as defined in claim 27 wherein said known general rules of mixing comprise:

adding phosphate salts before calcium salts;

basing calcium phosphate solubility upon the volume of solution in the prescription admixture at the time calcium is added; and,

adding calcium last to a prescription admixture.

29. A method as defined in claim 26 wherein said order determining step further comprises determining the order of admixing whereby components within groups that are compatible with one another are added sequentially to the final container, so that the number of rinses are minimized, the rinses being made to cleanse the hollow transfer means near the final container due to incompatibility of a component of one group relative to a component in another group that is next in order to be transferred.

30. A method as defined in claim 24 wherein said step of identifying and determining the amounts of the pharmaceutical components further comprises identifying lipids as a component of the prescription admixture, and providing the user with the option of terminating the preparation of the prescription admixture if the user so elects.

31. A method as defined in claim 30 wherein a warning is issued in the event the lipid containing prescription admixture is not terminated, which warning is that a next to be prepared prescription admixture may exhibit a hazy appearance because of the presence of lipids.

GREER, BURNS & CRAIN, LTD.
300 South Wacker Drive, Suite 2500
Chicago, IL 60606

Image

PATENT APPLICATION

ATTORNEY DOCKET NO. NU-5532

IN THE
UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Kircher et al.

Confirmation No.: 3314

Application No.: 09/729,498

Examiner: Gordon, Brian R.

Filing Date: Dec. 4, 2000

Group Art Unit: 1743

Title: METHOD AND APPARATUS FOR CONTROLLING THE STRATEGY OF COMPOUNDING PHARMACEUTICAL ADMIXTURES

Mail Stop Appeal Brief-Patents
Commissioner For Patents
PO Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF

Sir:

Transmitted herewith in **triplicate** is the Appeal Brief in this application with respect to the Notice of Appeal filed on Oct. 29, 2003.

The fee for filing this Appeal Brief is (37 CFR 1.17(c)) $330.00. A check in the amount of $330.00 is enclosed.

(complete (a) or (b) as applicable)

The proceedings herein are for a patent application and the provisions of 37 CFR 1.136(a) apply.

( ) (a) Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)-(d) for the total number of months checked below:

- ( ) one month
- ( ) two months
- ( ) three months
- ( ) four months

( ) The extension fee has already been filled in this application.

(X) (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

Please charge to Deposit Account 07-2069 the sum of _____. At any time during the pendency of this application, please charge any fees required or credit any over payment to Deposit Account 07-2069 pursuant to 37 CFR 1.25. Additionally please charge any fees to Deposit Account 07-2069 under 37 CFR 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees. A duplicate copy of this sheet is enclosed.

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Respectfully submitted,

By _____
Roger D. Greer

Attorney/Agent for Applicant(s)
Reg. No. 26,174

Date: December 10, 2003

Telephone No.: (312) 360-0080

NU-5532

PATENT

IN THE UNITED STATES PATENT AND TRADMARK OFFICE

Applicant:	Kircher et al.
Serial No.:	09/729,498
Filed:	December 4, 2000
For:	METHOD AND APPARATUS FOR CONTROLLING THE STRATEGY OF COMPOUNDING PHARMA-CEUTICAL ADMIXTURES
Group Art Unit:	1743
Examiner:	Gordon, Brian R.

I hereby certify that this paper is being deposited with the United States Postal Services as FIRST-CLASS mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date.

12/9/03 Reg D Green
Date Registration No. 28174

APPELLANT'S BRIEF ON APPEAL UNDER 37 C.F.R. §1.192

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Appeal Brief is in support of Applicant's Notice of Appeal dated October 29, 2003 from the final rejection dated October 6, 2003.

APPEAL BRIEF

REAL PARTY IN INTEREST

The real party in interest in this application is Baxter International Inc., One Baxter Parkway, Chicago, IL 60015.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences which will directly affect, be directly affected by, or have any bearing on the Board's decision in this pending appeal.

STATUS OF CLAIMS

This application was originally filed with 31 claims, only one of which has been amended, namely, claim 11 to correct a grammatical error. The rejections of all claims 1-31, inclusive, are appealed.

SUMMARY OF THE INVENTION

The present invention is an improved method and apparatus for preparing and accounting for parenteral nutritional solutions and for reducing instances of incompatibility, which preferably includes a software implementation of the method that will accommodate

many known active ingredients and other components that are set forth in various prescription admixtures. The apparatus and method implement strategies for preparing prescriptions for parenteral admixtures, for controlling the compounding apparatus, and for properly accounting for the prescribed admixture, with the strategies being implemented in computer software.

More particularly, the invention involves an apparatus (or method) for controlling pharmaceutical compounders that transfer prescribed amounts of pharmaceutical components from individual source containers to a final container to prepare a prescription admixture, that comprises computing means having a memory for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, with the memory includes data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, as well as data concerning the operating characteristics of the compounders. The computing means receives a prescription admixture, identifies the pharmaceutical components of it, determines the compatibility of the pharmaceutical components relative to one another, determines the order in which the components are transferred in preparing the prescription admixture, and communicates the instructions for preparing the prescription admixture to the compounders that are to be used in preparing the prescription admixture.

With regard to reading the claim elements on the specification, the following claim charts for claims 1 and 24 is believed to be instructive:

Claim	Specification
1. Apparatus (Fig. 1, ref 10) for use in controlling the operation of at least one pharmaceutical compounder (Fig. 1, ref 10) adapted to selectively transfer prescribed amounts of pharmaceutical components from individual source containers (Fig. 2, ref 30; Fig. 3, ref 56) through elongated hollow transfer means (Fig. 2, ref 32; Fig. 3, ref 54) to a final container Fig. 2, ref 46; Fig. 3, ref 58) in order to prepare a prescription admixture, said apparatus comprising:	Pg 10, ln 25 to pg 11, ln 14
computing means having memory means for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, said memory means including data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, and data concerning the operating characteristics of at least one of the compounders that the apparatus is adapted to control;	pg 11, ln 3-14. Generally: pg 15, ln 12 to pg 18, ln 5. Compatability of final prescription: pg 18, ln 13 to pg 19, ln 7. Calcium phosphate: pg 19, ln 7 to pg 21, ln 4. Compatability during compounding: pg 21, ln 5 to pg 22, ln 3. "Data relating..": pg 22, ln 4 to pg 23, ln 15. "operating characteristics...": pg 25, ln 13 to pg 26, ln 18.

said computing means including at least one communication port for establishing a communication link with each compounder that is to be controlled;	pg 11, ln 7-12. Fig. 1, ref 22.
said computing means being adapted to receive a prescription admixture, identify the pharmaceutical components thereof, determine the compatibility of the pharmaceutical components relative to one another, determine the order in which the components are transferred in preparing the prescription admixture, and communicate the instructions for preparing the prescription admixture to the compounders that are to be used in preparing the prescription admixture.	"receive and identify": pg 16, ln 1 to pg 17, ln 13. "determine compatibility": pg 18, ln 13 to pg 19, ln 7 and pg 21, ln 5 to pg 22, ln 3. "determine order": pg 23, ln 11 to pg 24, ln 25. "communicate instructions": pg 28, ln 2-7; pg 27, ln 6-8; pg 35, ln 11-19.

24. A method of controlling the operation of at least one pharmaceutical compounder (Fig. 1, ref 12, 14, 16) adapted to selectively transfer prescribed amounts of pharmaceutical components from individual source containers (Fig 2, ref 30, Fig 3, ref 56) through elongated hollow transfer means (Fig 2, ref 32, Fig 3, ref 54) to a final container (Fig 2, ref 46, Fig 3, ref 58) in order to prepare a prescription admixture, the method utilizing a computing means having memory means (Fig. 1, 10) for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, with the memory means including data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, and data concerning the operating characteristics of at least one of the compounders that the apparatus is adapted to control, the computing means including at least one communication port for establishing a communication link with each compounder that is to be controlled, the method comprising the steps of:

"selectively transfer": pg 16, ln 1 to pg 17, ln 13. "data relating..": pg 22, ln 4 to pg 23, ln 15. pg 11, ln 3-14. "operating characteristics...": pg 25, ln 13 to pg 26, ln 18. "communication port": pg 11, ln 7-12. Fig. 1, ref 22

receiving a prescription admixture in the computing means;	"receive and identify": pg 16, ln 1 to pg 17, ln 13.
identifying and determining the amounts of the pharmaceutical components of the prescription admixture;	"receive and identify": pg 16, ln 1 to pg 17, ln 13.
determining the compatibility of the pharmaceutical components relative to one another;	"determine compatibility": pg 18, ln 13 to pg 19, ln 7 and pg 21, ln 5 to pg 22, ln 3.
determining the order in which the components are transferred during the preparation of the prescription admixture; and,	"determine compatibility": pg 18, ln 13 to pg 19, ln 7 and pg 21, ln 5 to pg 22, ln 3.
communicating the instructions for preparing the prescription admixture to the at least one compounder that is to be used in preparing the prescription admixture.	"communicate instructions": pg 28, ln 2-7; pg 27, ln 6-8; pg 35, ln 11-19.

ISSUES PRESENTED

1. Whether claims 1-4, 10, 24-27 were properly rejected under 35 U.S.C. § 102(b) as being anticipated by Lewis et al. U.S. Patent No.5,228,485.

2. Whether claims 5-23 and 28, 30-31 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Lewis et al. as applied to claims 1-4, 10, 24-27

and 29 above and further in view of *Multitask Operating System for Automix® Compounders Version 2.30*, Baxter, May 1999.

GROUPING OF CLAIMS

Applicants contend that claims 1-5, 10-12 and 24-27 stand or fall together. Applicants also contend that claims 6-9 and 28 stand or fall together; claims 9, 13, 30 and 31 stand or fall together; claim 14 alone stands or falls; claims 15-18 stand or fall together; claims 19-21 stand or fall together; claim 22 alone stands or falls; claim 23 alone stands or falls; and claim 29 alone stands or falls.

ARGUMENT

I. The rejection of claims 1-4, 10, 24-27 under 35 U.S.C. § 102(b) as being anticipated by Lewis et al. U.S. Patent No.5,228,485. was improper.

The examiner's rejection of claim 1 on the basis of the Lewis et al. U.S. Patent No.5,228,485 (hereinafter "Lewis") is improper because it grossly exaggerates the Lewis reference far beyond what is justified. While the examiner has provided extensive comments concerning Lewis, it is clear that neither Lewis nor the Baxter reference used in the § 103 rejections of other claims, anticipate, teach or suggest several features of the claims, including the two independent claims 1 and 24.

The examiner's characterization of the Lewis reference misrepresents and distorts the functionality and capabilities of the prior art that is relied upon. Applicants are well aware of the content of this prior art because the Lewis patent is assigned to Clintec Nutrition Co., which is related to the assignee of the present invention and the Baxter reference is an operating manual of one of the assignee's own products that is also referred to in the present application.

The present invention significantly advances the state of the art and includes features and functionality that are totally missing in Lewis and Baxter. During the prosecution of this application the examiner had underlined the word "incompatible" several times during the characterization of the Lewis reference as if the knowledge that some drugs are not compatible with one another, in and of itself, is significant to the present invention. It simply is not.

Claim 1 claims an apparatus for use in controlling the operation of at least one pharmaceutical compounder which comprises, *inter alia*, "computing means including memory means for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, said memory means including data relating to a plurality of pharmaceutical components" and wherein "said computing means being adapted to receive a prescription admixture, identify the pharmaceutical components thereof, determine the compatibility of pharmaceutical components relative to one another, determine the order in which the components are transferred in preparing the prescribed admixture".

As is clearly set forth in the claim, it is the *computing means* that performs these functions, not a technician or operator. As is set forth in the specification, data relating to the pharmaceutical components is stored in the memory means and when a prescription is input into the apparatus, the computing means identifies the pharmaceutical components, determines their compatibility relative to one another and determines the order in which the components are transferred in preparing the prescription admixture. This is done in the course of its operation.

Lewis simply does none of this. The Lewis apparatus must be programmed by an operator using a keyboard and possibly another computer, but neither the master microprocessor nor the pumping microprocessor has the capability to identify the specific pharmaceutical components, determine their compatibility and determine the order in which the components are transferred to the final bag during compounding. To the extent that incompatibility of components is an issue, it must be determined to be so by the operation during the input process. The processing means of either of the Lewis or Baxter references cannot determine incompatibility. There is no discussion whatsoever in either reference about a processing means determining compatibility or determining the order of transfer of components because neither of them has this functionality. Lewis alludes to the compatibility issue at column 31, lines 7-10 where it states "normally, a rinse will not be conducted unless the next fluid to be pumped is incompatible with the previous fluid, or if the previous fluid pumped was the last fluid to be pumped." In the rinse operation discussion

at column 31, lines 58-64, it is clear that rinsing is operator defined: "As can be seen in Fig. 37, the first function performed during the rinsing operation is to perform a check to determine if the chamber needs to be rinsed after fluid has been transmitting from a particular source container. *An operator of the device may indicate that a rinse is required when information is being entered into the device*".

There is also little discussion as to the order in which components are transferred. Presumably, the order can be controlled, but it is done *by an operator* during setup. At column 20, lines 7-10 of Lewis, it states "the keyboard programming mode is the mode in which *an operator can input information* into the device to cause the device to transfer specific amounts of fluid from specific individual source containers in the receiving container." Also, at column 21, lines 13-20, the operation is described: "the *programmer may then use the keyboard illustrated in Fig. 22 to program* the amount of fluid to be transferred from that particular source container to the receiving container. The programmer may either enter the volume or the specific gravity of the fluid to be transferred. Typically, *during initial setup of the device, the specific gravity for each source container will be initially programmed by the operator.*" And finally, at column 21, lines 45-47, "*after the operator has completed entering information* into the device for all the source containers, the operator may then press the start key 284."

It is clear that the Lewis apparatus only operates in a particular manner that is established by the operator programming its operation. The operator keys in components and

presumably their order as a result of operator knowledge of compatibility or incompatibility of components relative to one another determines the order in which they are transferred and if the operator believes that a rinse should be done, programs that as well. The Baxter reference does not supply any of the deficiencies of Lewis. For the above reasons, claim 1 is neither anticipated, taught nor suggested by Lewis, Baxter, applied singularly or in combination with any of the other references of record.

Independent claim 24 is directed to a method for controlling the operation of at least one pharmaceutical compounder wherein the method utilizes a computing means having memory means for storing, *inter alia*, data relating to a plurality of pharmaceutical components that may be transferred to prepare the prescription admixture and which comprises the steps of identifying and determining the amounts of the pharmaceutical components of the prescription admixture, determining the compatibility of the pharmaceutical components relative to one another as well as the step of determining the order in which the components are transferred during the preparation of the prescription admixture. The computing means performs these identifying and determining steps. Lewis simply does not perform these steps. To the extent that they are carried out at all, they are carried out by an operator and certainly not by the microprocessors in the Lewis system. For these reasons as well as the reasons more fully described with regard to claim 1, it is believed that claim 24 is neither anticipated, taught nor suggested by Lewis or Baxter, applied singularly or in combination with one another or with the other references of record.

Claim 2 recites the functionality that the computing means is adapted to convert the amount of each component to a measure in which the compounder that is to prepare the prescription and mixture is able to transfer. This is simply not taught or suggested by Lewis. Lewis is a self-contained system which requires inputting that is done by a keyboard entry device. The only reference to another source is that "another method of entering the information into the device is through a computer terminal . . .", column 19, lines 14-21. The functionality of claim 2 is not addressed and therefore cannot be taught or suggested by Lewis, Baxter or any of the other references of record.

Claim 3 recites that the computing means is adapted to convert amounts of component volume set forth in the prescription admixture to a weight measure by multiplying the specific gravity of the component by the volume set forth in the prescription admixture. Lewis is not believed to teach or suggest this feature for the reason that an operator either inputs volume or specific gravity information into the apparatus during initial setup of the apparatus (column 21, lines 15-18).

Claim 4 is also not taught or suggested by any of the references of record. Neither Lewis nor Baxter have data relating to a plurality of pharmaceutical components that comprise a database having a plurality of compatibility groups as well as data specifying the compatibility and/or incompatibility of each group with respect to the other groups. It is simply not present or suggested by either reference.

Claim 5 further recites that at least the first one of the compatibility groups comprises components which include lipids and the second one of said compatibility groups comprises a component that is sterile water. Again neither Lewis nor Baxter have a database, much less a database that suggests these characteristics.

The Group consisting of Claims 9, 13, 30 and 31

Claim 9 specifies further functionality relating to the order of transfer that can vary depending upon whether a component that contains lipids is present in the prescription. The microprocessors of the Lewis or Baxter systems simply are not programmed to perform this functionality, and simply do not even remotely suggest this capability.

Claim 13 cites additional functionality wherein the computing means is adapted to examine the prescription admixture and determine whether lipid components are a part of it as well as making other determinations as recited. Neither Lewis, Baxter nor any of the other references even remotely teach or suggest this functionality.

With regard to claims 30 and 31, these claims were rejected under 35 U.S.C § 103 as being obvious over Lewis and Baxter. Nontheless, the functionality set forth in these claims is similar to that set forth in claims 9 and 13, and for the same reasons it is believed that these claims are not remotely taught or suggested by any of these references of record.

II. The rejection of claims 5-23 and 28, 30-31 under 35 U.S.C. § 103(a) as being unpatentable over Lewis et al. as applied to claims 1-4, 10, 24-27 and 29 above and further in view of *Multitask Operating System for Automix® Compounders Version 2.30*, Baxter, May 1999 was improper.

The Group consisting of claims 6-8 and 28.

With regard to claim 6, neither Lewis nor Baxter even remotely teach or suggest the computing means determining the order in which components are transferred so that the order is in accordance with a set of general rules of order of admixing as specified in this claim. These references do not have computing means that determine the order of transfer as set forth above, and also certainly do not determine the order such that it is in accordance with a set of general rules of order of admixing.

Claim 7 further specifies the features and functionality of the computing means determining the number and location of rinses that are to be made during the order of transfer of components. It simply is not taught or suggested by Lewis or Baxter or any of the other references of record. The number and location of rinses is decided by and is manually entered by an operator for every prescription.

Claim 28 is similar to claim 6 and should be allowable for the same reasons.

Claim 14

Claim 14 describes the functionality of the computing means being adapted to receive a plurality of prescription admixtures and to order them into a queue for preparation

and to reorder them based upon commonality of predetermined components as recited in the claim. Neither Lewis, Baxter nor any of the other references of record even remotely teach or suggest this functionality.

The Group consisting of claim 15-18

Claim 15 recites that the computing means is adapted to retrieve data relating to a patient profile as well as data relating to a plurality of categories of patients and make comparisons as recited in the claims. Lewis and Baxter simply do not have this capability and therefore cannot teach or suggest this claim.

With regard to claim 18, it is believed that Lewis and Baxter do not teach or suggest preparing a report containing the information as set forth in this claim.

The Group consisting of claims 19-21

Claim 19 defines added functionality that is performed by the computing means wherein it is adapted to retrieve data relating to a patient profile for which a prescription admixture is to be prepared, wherein the patient profile data includes at least the patient's name, age and weight, said computing means being adapted to retrieve data relating to limits of amounts of admixture components that can be added to a particular patient's prescription admixture, said computing means being adapted to compare the amounts of components in a prescription admixture for a patient and require an authorized entry of data explaining the

rationale of exceeding one or more of such limits. Neither Lewis or Baxter have anything close to this functionality, particularly with regard to requiring an authorized entry of data explaining the rationale of exceeding one or more of such limits and therefore fail to teach or suggest this claim.

Claim 22

Claim 22 further specifies that said memory means includes data relating to the amount of fluid that is required to prime the compounder from a source container through the elongated hollow transfer means to the final container, said processing means being adapted to increase the amount of a component by the amount that is required to prime the compounder. There is nothing in Lewis or Baxter that even remotely suggests increasing the amount of a component by the amount that is required to prime the compounder.

Claim 23

Claim 23 further specifies that the processing means is adapted to receive a switchable input relating to the preparation of an admixture prescription that calls for a first component in a predetermined amount, an amount of diluent for said first component and one or more additional components in relatively small amounts, wherein the total admixture prescription is to be a predetermined total amount, said computing means being adapted to use the volume of said one or more additional components in relatively small amounts as a

substitute for the same volume of diluent so that the predetermined total amount is not exceeded. This functionality of using the volume of said one or more additional components in relatively small amounts as a substitute for the same volume of diluent so that the predetermined total amount is not exceeded is not remotely suggested by Lewis or Baxter.

Claim 29

Claim 29 further defines the order determining step to comprise determining the order of admixing whereby components within groups that are compatible with one another are added sequentially to the final container, so that the number of rinses are minimized, the rinses being made to cleans the hollow transfer means near the final container due to incompatibility of a component of one group relative to a component in another group that is next in order to be transferred. While neither Lewis or Baxter have a computing means that determine the order of admixing as previously discussed, they certainly do not have the additional functionality of using sequentially adding compatible groups to minimize the number of rinses that are required. Neither Lewis nor Baxter remotely teach or suggest the functionality described in this claim.

CONCLUSION

For the above reasons, the Applicant respectfully requests that the Board reverse the Examiner's § 102 and 103 rejections of all pending claims 1-31

Respectfully submitted,

GREER, BURNS & CRAIN, LTD.

By

Roger D. Greer
Registration No. 26,174

December 10, 2003

300 South Wacker Drive, 25th Floor
Chicago, Illinois 60606
(312) 360-0080
Facsimile: (312) 360-9315

APPENDIX

1. Apparatus for use in controlling the operation of at least one pharmaceutical compounder adapted to selectively transfer prescribed amounts of pharmaceutical components from individual source containers through elongated hollow transfer means to a final container in order to prepare a prescription admixture, said apparatus comprising:

computing means having memory means for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, said memory means including data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, and data concerning the operating characteristics of at least one of the compounders that the apparatus is adapted to control;

said computing means including at least one communication port for establishing a communication link with each compounder that is to be controlled;

said computing means being adapted to receive a prescription admixture, identify the pharmaceutical components thereof, determine the compatibility of the pharmaceutical components relative to one another, determine the order in which the components are transferred in preparing the prescription admixture, and communicate the instructions for preparing the prescription admixture to the compounders that are to be used in preparing the prescription admixture.

2. Apparatus as defined in claim 1 wherein said computing means is adapted to convert the amount of each component to a measure in which the compounder that is to prepare the prescription admixture is able to transfer.

3. Apparatus as defined in claim 2 wherein said computing means is adapted to convert amounts of component volume set forth in a prescription admixture to a weight measure by multiplying the specific gravity of the component by the volume set forth in the prescription admixture.

4. Apparatus as defined in claim 1 wherein said data relating to a plurality of pharmaceutical components comprises a database having a plurality of compatibility groups, with each group having at least one of said pharmaceutical components, said database also having data specifying the compatibility and/or incompatibility of each group with respect to other groups.

5. Apparatus as defined in claim 4 wherein at least a first one of said compatibility groups comprises components which include lipids, and a second one of said compatibility groups comprises a component that is sterile water.

6. Apparatus as defined in claim 4 wherein said computing means determines the order in which the components are transferred so that the order is in accordance with a set of general rules of order of admixing, which general rules comprise:

phosphate salts are added before calcium salts;

calcium phosphate solubility is made based upon the volume of solution in the prescription admixture at the time calcium is added; and,

calcium is the last additive to the prescription admixture.

7. Apparatus as defined in claim 6 wherein said computing means determines the number and location of rinses that are to be made during the order of transfer of components, with a rinse being a cleansing of at least a portion of the elongated hollow transfer means near the final container with a solution that is compatible with the next succeeding component that is to be transferred to the final container.

8. Apparatus as defined in claim 6 wherein said cleansing solution is taken from one of the individual source containers or the final container.

9. Apparatus as defined in claim 4 wherein said computing means includes at least one port for receiving input data for selecting whether a pharmaceutical component that includes lipids will determine the order of transfer such that the lipid containing component is transferred one of either first or last relative to all other pharmaceutical components.

10. Apparatus as defined in claim 1 wherein said communication link can be comprised of at least one of an internet connection, a local area network connection and a wireless connection.

11. Apparatus as defined in claim 1 wherein said apparatus is adapted to be used by users in at least two locations, wherein each location can have at least one compounder, and a printer for printing labels, a terminal with a display and entry device for inputting prescription admixtures and selectable settings relating to the operation of the apparatus and compounders.

12. Apparatus as defined in claim 11 wherein said computing means is adapted to control two compounders at each location, with one compounder being adapted to transfer components at a flow rate that is significantly higher than the other compounder.

13. Apparatus as defined in claim 9 wherein said computing means is adapted to examine the prescription admixture and determine whether lipid components are a part thereof, determine whether the user objects to the subsequent prescription admixture that will be prepared having a probable hazy appearance because of the presence of a lipid component in the prescription admixture presently being prepared, terminate the preparation of the prescription admixture in the event the user indicates an objection and issue a warning of such probable hazing in the event the user indicates no objection.

14. Apparatus as defined in claim 9 wherein said computing means is adapted to receive a plurality of prescription admixtures and order them into a queue for preparation, said computing means being adapted to examine each prescription admixture that is in the queue and determine the commonality of predetermined components therein, and to reorder the prescription admixtures in said queue to group together said prescription admixtures which have such commonality of predetermined components.

15. Apparatus as defined in claim 1 wherein said computing means is adapted to retrieve data relating to a patient profile for which a prescription admixture is to be prepared, wherein the patient profile data includes at least the patient's name, age and weight, said computing means being adapted to retrieve data relating to a plurality of categories of patients, with each category containing predetermined limits of admixture components that are specific to each category, said computing means being adapted to compare the amounts of components in a prescription admixture for a patient in one of said categories and provide a signal when a component is outside of the predetermined limits for said component in the prescription admixture.

16. Apparatus as defined in claim 15 wherein said categories of patients comprise adult, pediatric, neo-natal and premature patients.

17. Apparatus as defined in claim 15 wherein said signal is adapted to prevent the prescription admixture to be prepared.

18. Apparatus as defined in claim 15 wherein said patient's profile data further includes a history of the patient's weight and admixture prescriptions over a period of time, said processing means being adapted to prepare a report concerning the patient, including a projection of the patient's weight at some time in the future.

19. Apparatus as defined in claim 1 wherein said computing means is adapted to retrieve data relating to a patient profile for which a prescription admixture is to be prepared, wherein the patient profile data includes at least the patient's name, age and weight, said computing means being adapted to retrieve data relating to limits of amounts of admixture components that can be added to a particular patient's prescription admixture, said computing means being adapted to compare the amounts of components in a prescription admixture for a patient and require an authorized entry of data explaining the rationale of exceeding one or more of such limits.

20. Apparatus as defined in claim 19 wherein an authorized entry of data is entry of data by at least a physician or pharmacist.

21. Apparatus as defined in claim 19 wherein an absence of required data explaining the rationale of exceeding one or more of such limits results in said computing means terminating the preparation of said admixture prescription.

22 Apparatus as defined in claim 1 wherein said memory means includes data relating to the amount of fluid that is required to prime the compounder from a source container through the elongated hollow transfer means to the final container, said processing means being adapted to increase the amount of a component by the amount that is required to prime the compounder.

23. Apparatus as defined in claim 1 wherein said processing means is adapted to receive a switchable input relating to the preparation of an admixture prescription that calls for a first component in a predetermined amount, an amount of diluent for said first component and one or more additional components in relatively small amounts, wherein the total admixture prescription is to be a predetermined total amount, said computing means being adapted to use the volume of said one or more additional components in relatively small amounts as a substitute for the same volume of diluent so that the predetermined total amount is not exceeded.

24. A method of controlling the operation of at least one pharmaceutical compounder adapted to selectively transfer prescribed amounts of pharmaceutical components from individual source containers through elongated hollow transfer means to a final container in order to prepare a prescription admixture, the method utilizing a computing means having memory means for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, with the memory means including data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, and data concerning the operating

characteristics of at least one of the compounders that the apparatus is adapted to control, the computing means including at least one communication port for establishing a communication link with each compounder that is to be controlled, the method comprising the steps of:

receiving a prescription admixture in the computing means;

identifying and determining the amounts of the pharmaceutical components of the prescription admixture;

determining the compatibility of the pharmaceutical components relative to one another;

determining the order in which the components are transferred during the preparation of the prescription admixture; and,

communicating the instructions for preparing the prescription admixture to the at least one compounder that is to be used in preparing the prescription admixture.

25. A method as defined in claim 24 wherein the step of identifying and determining the amounts includes the step of converting the amount of each component to a measure in which the compounder that is to prepare the admixture prescription is able to transfer.

26. A method as defined in claim 24 wherein the data relating to a plurality of pharmaceutical components comprises a database of pharmaceutical components that are categorized into a plurality of groups, with the components of each group having common compatibility characteristics, said database having data specifying the compatibility and/or incompatibility of each group relative to other groups, said compatibility determining step further comprising:

examining the admixture prescription to identify the particular groups of components that are present therein, and the compatibility characteristics of each group relative to the other identified groups.

27. A method as defined in claim 26 wherein said order determining step further comprises: determining the order of admixing so that components within groups that are compatible with one another are added concurrently or sequentially to the final container consistent with known general rules of mixing.

28. A method as defined in claim 27 wherein said known general rules of mixing comprise:

adding phosphate salts before calcium salts;

basing calcium phosphate solubility upon the volume of solution in the prescription admixture at the time calcium is added; and,

adding calcium last to a prescription admixture.

29. A method as defined in claim 26 wherein said order determining step further comprises determining the order of admixing whereby components within groups that are compatible with one another are added sequentially to the final container, so that the number of rinses are minimized, the rinses being made to cleanse the hollow transfer means near the final container due to incompatibility of a component of one group relative to a component in another group that is next in order to be transferred.

30. A method as defined in claim 24 wherein said step of identifying and determining the amounts of the pharmaceutical components further comprises identifying lipids as a component of the prescription admixture, and providing the user with the option of terminating the preparation of the prescription admixture if the user so elects.

31. A method as defined in claim 30 wherein a warning is issued in the event the lipid containing prescription admixture is not terminated, which warning is that a next to be prepared prescription admixture may exhibit a hazy appearance because of the presence of lipids.